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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/331,261	07/13/99	PEREGRINO FERREIRA	P 41823

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EXAMINER	
ZEMAN, R	
ART UNIT	**PAPER NUMBER**
1645	11

DATE MAILED: 07/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.	Applicant(s)
09/331,261	Ferreira et al
Examiner	**Group Art Unit**
Robert A. Zeman	1645

THE PERIOD FOR RESPONSE: [check only a) or b)]

a) ☐ expires _____ months from the mailing date of the final rejection.

b) ☒ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on _____ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on *May 30, 2000* **has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:**

☒ The proposed amendment(s):

☐ will be entered upon filing of a Notice of Appeal and an Appeal Brief.

☒ will not be entered because:

☒ they raise new issues that would require further consideration and/or search. (See note below).

☒ they raise the issue of new matter. (See note below).

☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: *See attached*

☐ Applicant's response has overcome the following rejection(s):

☐ Newly proposed or amended claims _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attached

☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: _____

Claims objected to: _____

Claims rejected: *1-3*

☐ The proposed drawing correction filed on _____ ☐has ☐has not been approved by the Examiner.

☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ .

☒ Other *Interview Summary*

DETAILED ACTION

New Issues

Proposed claim 4 would raise new matter issues since cited portions of specification do not read exactly as new claim language. Further, new claim 4 is indefinite as not all recited combinations of solid support and materials are known to exist.

Applicant's request for reconsideration has been considered but does NOT place the application in condition for allowance for the following reasons:

Applicant argues that the reactivity of gp90 peptides differs depending on the length of the peptide and that the sequence of EIAV gp90 synthetic peptides shows different immune reactivity. Applicant further argues that the nucleic acid deposit in GENBANK (Reis et al., 1996) is only a fraction of the full length sequence disclosed in the instant application and that said deposited nucleic acid sequence predicted two additional His amino acids in the N-terminal and a divergency of the other 38 amino acids when compared to other GENBANK deposit sequence and that the deposited sequence is close in length to the peptides used by Peterson et al. and Ball et al. Applicant further argues that Peterson et al., does not support the rejection since the protein domain or immune dominant region is not the same and that the proposed amino acid length, as well as the one described by Ball et al. and predicted amino acid sequence from deposit in GENBANK (Reis et al., 1996), is a peptide. Applicant then argues that Ball et al. disclose that the use of peptides as antigens is designed to "identify specific linear sites which are immunogenic in the native protein antigen; that the particular conformational properties of the

peptide antigen may vary from the native protein structure and thus reduce antibody binding; that it is necessary to consider the full length protein to which the peptide can be used as a complement in retroviral immunoassays; and that the recognition of peptide antigens by sera of HIV-1 infected individuals varies among the infected population during the course of the infection in a particular person. In summary, Applicant argues that the claimed invention relates to a non-glycosylated recombinant protein in immunoenzymatic assays, with no need for glycosylation, for identification of antibodies against the gp90 native surface protein of the EIA virus, and that the claimed recombinant protein reacts with immunosera because it is a full length protein and thus has the proper conformational structure and that it will avoid histocompatibility complex polymorphism since it is not glycosylated.

Applicant's arguments have been considered and have been found to be non-persuasive for these reasons:

1. Applicant is reminded the rejection was based on the **combination** of the cited references. In particular, Reis et al. disclose that the source of material is EIA recombinant gp90 protein; Ball et al. disclose *inter alia* that the predominant antibody response in infected animals is to the peptide portion of gp90; Peterson et al. disclose recombinant EIA antigen and assay formats. Further, a reference is **available** for everything taught therein and not merely for working examples or preferred embodiments.

2. Additionally, Applicant's arguments based on purported deficiencies in the sequences disclosed by Ball et al. and Reis et al., rely on limitations not found in the claims. The claims

recite "providing recombinant gp90 envelope protein from the equine infectious anemia virus" and do not require a particular protein size or sequence or that the protein not be glycosylated. Even if the claims were amended to recite such features, it is noted that Ball et al. teaches that the antibody response is conveyed by the conformational structure determined by the peptide sequence and not the oligosaccharide portion of the molecule. As Applicant himself has pointed out in Paper No. 7, "the skilled artisan would have no difficulty in making gp90" and that "those skilled in the art well know how to make the material necessary for practice of the present method". Consequently, the rejection of claims 1-3 are maintained for reason of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Anthony Caputa, can be reached at (703)308-3995.

Robert A. Zeman

June 26, 2000

DONNA WORTMAN
PRIMARY EXAMINER